K101131

JUN 17 2010

510(k) Summary

Applicant / Manufacturer:	Cosman Medical, Inc. 76 Cambridge St., Burlington MA 01803. USA Tel. 781-272-6561, Fax 781-272-6563
Contact Person:	Louis Falcone, Director of RA LFalcone@cosmanmedical.com
Registration Number:	3004867882
Date Prepared:	April 19, 2010
Trade Names:	Fiducial Markers
Dated:	April 19, 2010
Common Name:	COSMAN MEDICAL Ball Fiducial Markers
Classification:	CFR 892.5050, Class II, Medical charged-particle radiation therapy system Product Code: IYE
Performance Standard:	No applicable performance standards have been issued under section 514 or under section 513(b) of the Food, Drug, and Cosmetic Act.
Predicate Device:	CIVCO MEDICAL SOLUTIONS, Fiducial Markers (K071614)

Intended Use:
The Ball Fiducial Markers are intended to be implanted into the body to accurately visualize and constitute the reference frame for stereotactic radiosurgery and radiotherapy target localization. Specifically, they can be used in intracranial diseases such as gliomas, neuromas, meningiomas, astrocytomas, arteriovenous malformations, and metastatic carcinomas. Additionally, they can be used in the body for treating hepatic, pancreatic, retroperitoneal, paraspinal, skeletal, prostatic and breast tumors.

Comparison to Predicate:
The Cosman Ball Fiducial Markers have been compared to previously 510(k) cleared devices with respect to intended use and technological characteristics. The Cosman Ball Fiducial Markers have similar physical and technical characteristics to the predicate devices. The technical characteristic comparison chart provided in this 510(k)

notification shows that the Cosman Ball Fiducial Markers are substantially equivalent to the **CIVCO MEDICAL SOLUTIONS,** Fiducial Markers predicate device and are safe and effective for indicated intended use.

Safety and Effectiveness: The comparison to the predicate device demonstrates that the Cosman Ball Fiducial Markers are safe and effective and are substantially equivalent to the **CIVCO MEDICAL SOLUTIONS** Fiducial Markers predicate device.

Submitted By: Name: Louis Falcone

Signature

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

JUN 17 2010

Mr. Louis Falcone
Director of RA
Cosman Medical, Inc.
76 Cambridge Street
BURLINGTON MA 01803

Re: K101131
Trade/Device Name: Cosman Ball Fiducial Markers
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: April 12, 2010
Received: April 22, 2010

Dear Mr. Falcone:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K101131

Device Name: **Cosman Ball Fiducial Markers**

Indications For Use:

"The Ball Fiducial Markers are intended to be implanted into the body to accurately visualize and constitute the reference frame for stereotactic radiosurgery and radiotherapy target localization. Specifically, they can be used in intracranial diseases such as gliomas, neuromas, meningiomas, astrocytomas, arteriovenous malformations, and metastatic carcinomas.

Additionally, they can be used in the body for treating hepatic, pancreatic, retroperitoneal, paraspinal, skeletal, prostatic and breast tumors."

Prescription Use __X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ OIVD

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(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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